Environmental Protection Division Laboratory

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Lab Director Approval: Moone 08/19/2021

QA Manager Approval: Deffney Moone 08/19/2021

Standard Operating Procedure for Control Charts and Control Limits

Access to this SOP shall be available within the laboratory for reference purposes; the official copy of this SOP resides on the official Georgia EPD website at https://epd.georgia.gov/aboutus/epd-laboratory-operations. Printed copies of this SOP will contain a watermark indicating the copy is an uncontrolled copy.

1.0 Control Charts

1.1 General Guidelines

Control charts will be generated twice annually (January and July). They are to be based on the previous 24 months of data (e.g. the January 2007 charts will be based on samples submitted between 1/1/05 thru 12/31/06). If there are not at least 10 points available from a 24-month period, 36 months of data may be used. If 36 months yields less than 10 points, further action will be determined on a case-by-case basis. SQC routines should be set to plot "ALL" points so that outliers may be easily determined (see below).

In those cases where 24-months of data would result in more than 500 data points, limit the data set to 500 points, but not less than 6 months (even if this results in more than 500 data points).

In the event of a significant change in instrumentation or method during the previous 24 months, the control charts, if the Manager feels it is appropriate and with the approval of the QA Manager, need not include data prior to the change.

Optionally, labs may produce more frequent control charts based on other time periods or displaying a different number of points for the purpose of monitoring their systems. These charts would be for internal use (such as determining that instrument maintenance was needed) within that lab and not for use in developing control limits.

Note: Analyses performed by Non-Drinking Water Standard Methods may default to method default limits instead of calculated control limits.

See Attached Memo by Phillip G. Mitchell titled "Instructions for Control Charting for 1st Semester 2012 (2012 JAN-JUN)" for detail Control Charting Procedures disregarding hand-written notations in section 7.14.

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1.2 Surrogate Control Charts

At a minimum, surrogates are to be charted for routine samples. Different routines will be needed from those used for target analyte spikes, as percent recovery is not calculated for surrogates in samples. In this case True Value concentrations are charted. This will work as all surrogate values in Labworks are adjusted as though the samples were ideal (exact sample size specified in the SOP and 100% solids for soils) in order for Labworks to determine and flag out of range values. This is a relatively easy process. I will provide any assistance needed to set this up.

1.3 Matrix Spike and Matrix Spike Duplicate Control Charts

Charts for Matrix Spike recoveries, and Matrix Spike Duplicate recoveries and precisions that are currently maintained or that may be required in the future will be generated from separate data sets consisting only of Matrix Spike and Matrix Spike Duplicate data. These data sets will also be based on the most recent 24-month data (limit 500 data points, minimum 6 months as discussed above).

To meet Drinking Water and other analyses requirements, we will begin calculating recoveries on all Matrix Spike Duplicates. Drinking Water methods require charting and control limits based on Matrix Spikes. These methods also require Matrix Spikes at a frequency of 10% and require that all Matrix Spike recoveries be within control limits. This means that we will have to calculate recoveries for Matrix Spike Duplicates.

While it is necessary to chart the MS/MSDs, it is reasonable to expect the limits to be broader than those of the LCS/LCSDs. Therefore, while control limits for MS/MSDs will be generated on control charts, actual MS/MSD limits to be used will be assigned the same limits as the LCS/LCSDs. LCS/LCSD limits will be used for batch validation according to the Data Validation SOP for each lab. We will LIMS comments as appropriate when MS/MSD results fall outside the LCS/LCSD control limits.

Test codes for MSD recoveries should be named beginning with \$RD or RD as is appropriate. To chart spike and duplicate recoveries, separate SQC routines will be needed for each. The data will then be combined in SWA-QA and charts produced afterwards.

LCSD recoveries will also be calculated, though LCSD recoveries will not be used for batch validation. Test codes for LCSD recoveries should be in the form \$L2 and L2. If an LCSD recovery falls outside LCS control limits, a corrective action will be initiated and a comment added in Labworks similar to the following:

\$L28082H - EPA 8082 - The LCSD had one compound, (PCB 1016 60% recovery, limits 65 - 120%) with a recovery outside acceptable control limits. The LCS recoveries were within acceptable control limits meeting QC requirements. 9-023108-123

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Sometimes QC samples may be associated with more than one batch. For example, the QC for pesticide waters may be associated with an 8081A and a 608 batch. In this case, the analyte list may be slightly different for each method/batch requiring different base test codes. In cases where multiple base test codes are to be charted together (overlapping compound list; compounds in both have same control limits) extra care must be taken to assure that compounds are matched up correctly when combining the data into a single NWA-QA data file for charting and calculating limits.

The QA Manager or LIMS Administrator will provide assistance, as needed.

Please note: LCSD recoveries are not to be calculated or charted if not specifically required by method unless it is noted in the SOP that this data is monitored for internal purposes only and not for batch data validation.

1.4 Control Chart LIMS Settings

1.4.1 Sample Selection Tab

1.4.1.1 Title Field: This SQC routine field will contain the base test code name and a brief description sufficient to identify the parameter or parameter group being charted. Examples: "\$8081H Pest H2O SW846-8081A MSD %Rec" or "TOCDW TOCs Drinking Water SM5310C LCSD %RPD". There is a limit of 40 characters; therefore highest priority will be given to identifying the base test code and the type of QC (LCS/LCSD or MS/MSD and recovery or precision). Lowest priority will be given to the exact test method.

1.4.2 Charts Tab

- 1.4.2.2 Individual Measurement and Range Checkbox: This box will be <u>checked</u> and select the Measurement button of the button group below it.
- 1.4.2.3 Display Checkbox: This box should be checked.
- 1.4.2.4 Print Checkbox: It is advised that this checkbox be unchecked unless you are sure that there will be no need to manually manipulate the data before generating the final charts.
- 1.4.2.5 No other checkboxes on the left side of the dialog should be checked.
- 1.4.2.6 Over write header and run files Checkbox: It is recommended that this remain unchecked.
- 1.4.2.7 Use pattern rules Checkbox: Do not check.
- 1.4.2.8 Use LABWORKS specifications Checkbox: This box should be unchecked. There are two reasons. Firstly, it adds unnecessary complexity to charts. Secondly, the specifications may be edited to show the maximum UCL + 50% and 50% of the minimum LCL for easy visual detection of outliers (see the discussion of outliers below). This is also the reason for not allowing Labworks to overwrite header and run files.



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- 1.4.2.9 Number of points to plot or ALL Field: This field will contain the text "ALL".
- 1.4.2.10 X-axis labeling and sorting options Group: Select Sample ID.
- 1.4.2.11 Nonnumeric results options Group: Select omit result from chart.
- 1.4.3 Chart Display Layout Tab
 - 1.4.3.1 No more than three charts stacked vertically should be selected.

1.5 Generating Control Charts

Option 1:

Data files may be generated from scratch each semi-annual charting sessions. In this case, 24 months of data would be generated, any initial manual manipulations performed (e.g. appending MSD recovery data to the MS data file) and charts generated. If this approach is used, the charts/data files must be scanned for outliers for the entire 24-month period and any outliers edited as noted below. The charts would then be regenerated, if any outliers had been found.

Option 2:

The first time these guidelines are implemented, a permanent 24-month data file would be generated. Once generated, the names of the .dat, .run and .hed files would be changed to something different from the SQC routine so that they would not be overwritten by the SQC routine later. Each semi-annual charting session, the data file(s) for the current 6 month period would be generated and combined as necessary (i.e. MS and MSD data combined), the charts/data files scanned for outliers and edited as noted below. This data would then be appended to the permanent data file, the oldest 6 months of data deleted and charts for the 24-month period generated.

Either approach will require that multiple SQC routines be created if spike and duplicate recoveries must be charted due to limitations of Labworks.

2.0 Control Limits

2.1 Methods with Pre-defined Limits

Non-Drinking Water Method: Control charts for these methods should have calculated limits displayed, but these are for informational purposes only. These charts should be treated as a tool for monitoring analytical systems, but there will be no formal guidelines for this review. Outliers (discussed below) are not a concern and therefore need not be addressed. The requirements for non-reportable QC (failed or extra) discussed below do apply to these methods.

Drinking Water Methods: Although most drinking water methods list pre-defined control limits and allow development of in-house control limits an option, section 7.2.8 of the

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<u>Manual for the Certification of Laboratories Analyzing Drinking Water</u> requires the development of in-house control limits from control charts.

2.2 Outliers

For EPD control charting, recovery outliers are defined as data points that are more than 200% recovery or less than 50% of the minimum recovery Lower Control Limit (LCL)¹. Precision outliers are defined as data points that are above 75% RPD. NWA-QA is set to use different characters for data points outside of control limits on control charts. A point can be outside of control limits and not considered to be an outlier by the EPD Lab unless it meets the criteria above.

Outliers must be manually changed to asterisks in the NWA-QA data files (any non-numeric data is represented with asterisks so that the will be ignored when calculating control limits). To determine if outliers are present, inspect the control charts generated and look for values outside of control limits (points represented by asterisks on the control charts). If such values exist, open the data file in NWA-QA, find those values and determine if they are outliers. After saving the data file, regenerate the control charts. Repeat this cycle until there are no more outliers (but there may be data points remaining that are outside of control limits). In almost every case, this should require only one cycle to accomplish.

Optionally, the data file can be edited to include specification values that will be plotted on the control charts in the same manner as UCLs and LCLs. If these specifications are set to 50% of the minimum LCL for the lower value and 200% for the upper value for recovery charts, outliers become immediately apparent, as they will be near or beyond these specification values. Once these specifications have been entered, the Labworks SQC routine must be set so as to prevent overwriting header and run files.

2.3 Control Limits

Once control charts have been developed, the control limits calculated with the final data points will be examined for reasonableness as follows (applies to in-house limits only):

- 2.3.1 For methods for which multiple laboratory limits are published in the method, inhouse calculated limits may never exceed the published limits.
- 2.3.1.1 The calculated limits are compared to in-house restrictions on limits.
- 2.3.1.2 For regular compounds, the UCL will not be less than 100% for recovery
- 2.3.1.3 For regular compounds, the UCL will not be less than 10% RPD for precision unless specified by method.
- 2.3.1.4 For regular compounds, the LCL will not be more than 90% for recovery unless specified by method.

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- 2.3.1.5 The LCL for precision is always zero.
- 2.3.1.6 Surrogates are not subject to the above specific lab-wide limitation.
- 2.3.1.7 Method/matrix specific in-house limitations may be established. For example, TO-11A currently has in-house restrictions that the UCL should not be less than 115% and the LCL should not be more than 85% for recoveries. These limits are reasonable for this analysis and any tighter limits would likely result in excessive failures.
- 2.3.1.8 Method/matrix specific limitations for surrogates may be set to not less than 100% if appropriate.
- 2.3.1.9 Such restrictions should be approved by the QA Manager and noted in the appropriate SOPs.
- 2.3.1.10 In lieu of formal in-house restrictions on limits, should it be concluded that the calculated limits would result in an unreasonable number of failures, the control limits may be adjusted to more reasonable values with approval of the QA Manager.
- 2.3.1.11 Adjustments and restrictions on limits are not intended to justify poor results.

2.4 Non-Reportable QC – Failed QC

In the past, whenever a set of QC failed and a batch required re-extraction, the QC data from the first failed batch has been ignored for purposes of charting and limits. This practice tends to result in unreasonably tight control limits. To rectify this, please implement the following:

- 2.4.1 If a batch of samples is re-extracted/re-prepared due to failed QC, the original failed QC (Blank, LCS, LCSD and if appropriate MS and MSD) will be logged into Labworks under a new and unique sample number. This sample will not be associated with any batches in Labworks. Appropriate QC test codes will be added (\$B..., \$LA..., \$LR..., etc., i.e. the same QC codes that were appropriate for the original batch had the QC passed) to calculate recoveries and precisions. Include all appropriate QC (i.e. include Blank and matrix test codes even if only the LCS failed).
- 2.4.2 The data from these samples will be entered into Labworks.
- 2.4.3 A failed QC may logged in as noted in the paragraphs above and later determined that the QC failed because of instrument or equipment failure, improper spiking, etc. that should not be reflected in control charts and control limits. Such QC samples should be voided and commented appropriately in the Sample Comment.
- 2.4.4 Log failed QC samples into Labworks with the following to facilitate cross reference searches:
- 2.4.4.1 Source ID: OCTracF
- 2.4.4.2 Source Description: Testcode-BatchNum (i.e. "\$8081S-36985")

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- 2.4.4.3 DNR Project: QCTrac
- 2.4.5 Sometimes QC samples may be associated with more than one batch. For example, the QC for pesticide waters may be associated with an 8081A and a 608 batch. In this case, the analyte list may be slightly different for each method/batch requiring different base test codes. Passing QC for such batches would be logged once for each method/batch, therefore the failed QC samples should be assigned QC test codes for each method. In such cases the Source Description should be in the form "\$8081H-45987 + \$608-45988".
- 2.5 Non-Reportable QC Extra QC Data

Occasionally, analysts prepare and run sets of LCSs that are not associated with batches. At the Manager's discretion, such samples may be logged into Labworks to provide additional data points for charting and control limits.

- 2.5.1 Any numeric result data associated with these samples that is recorded but should not be included in control charts should be appended with an asterisk as noted for failed OC above.
- 2.5.2 Log these samples into Labworks with the following to facilitate cross reference searches:
- 2.5.2.1 Source ID: QCTracX
- 2.5.2.2 Source Description: Base Testcode(s) (i.e. "\$8081S")
- 2.5.2.3 DNR Project: QCTrac

3.0 Final Approval

- 3.1 Control charts and updated control limits are to be submitted to the QA Manager for approval by January 31 of each year. New control limits are not to be implemented until SOPs or Appendices (typically Appendix A) have been revised, approved and reissued.
- 3.2 Mid-year control charts and control limits are to be submitted to the QA Manager for approval by July 31 of each year. Typically, new mid-year control limits are not to be implemented and are used for trend monitoring purposes only. However, new mid-year control charts and control limits may be implemented if needed.
- 3.3 The updating of control limits in Labworks should coincide as closely as possible (within one or two days afterwards, at most) with the issuance of SOPs and interim tables. However, samples that are analyzed while older criteria are in force must be reported against those criteria. Due to limitations of Labworks test codes may require temporary modification in order to assure that all samples are reported against the proper criteria.

Updates: Online revision statement added.

Memo Attachment:

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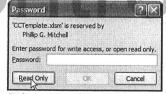
Georgia Department of Natural Resources

Environmental Protection Division Laboratory

Special QA Instruction Memo July 31, 2012

<u>Instructions for Control Charting for 1st Semester of 2012</u> (2012 JAN-JUN)

- 1. Read and understand SOP 6-025 Rev. 0, "Standard Operating Procedure for Control Charts and Control Limits".
- 2. Read and understand this memo.
- 2.1. Where the SOP and this memo conflict, this memo takes precedence over the SOP.
- 3. Due to Labworks limitations, a spreadsheet has been developed to perform proper QC charting.
- 3.1. The spreadsheet is named CCTemplate.xlsm. MS Excel 2007 or later must be installed to work with this spreadsheet. It is located in:
- 3.2. S:\CCData
- 3.3. The spreadsheet automatically limits the charted data points to the 500 most recent points or a minimum of 6 months if there are more than 500 points in the most recent 6 months, per the SOP.
- 3.4. This spreadsheet <u>does not</u> account for outliers. Handling of outliers will be addressed Section 9 of these instructions.
- 4. When the spreadsheet is opened, the following message will be displayed:



4.1.

4.2. Select "Read Only" to continue.

5. The spreadsheet main screen appears as follows:

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3	#	Selected	Valid		Date	Date					-
4	1				01/14/11	01/14/11					1
5	2										
6	3				File to Save:						
7	4										
8	5										
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5.1.

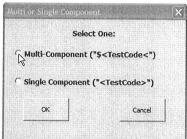
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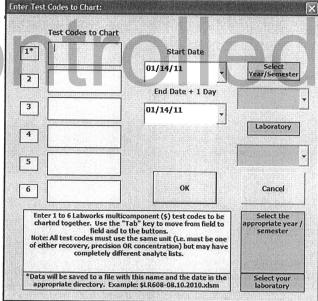
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- 5.2. Do not enter any data on this page! You should not be able to even if you try. Click the "Setup Control Charts" button to begin.
- 6. A choice between multicomponent ("\$") test and single component test will be presented:



- 6.1.
- 6.2. Select one or the other and press "OK" to continue.
- 7. Multicomponent Control Charts:
- 7.1. If multicomponent charting is selected, the following screen will be presented:



Copy

7.1.1.

- 7.2. Test codes are entered in the cells labeled 1-6. The first cell ("1*") should be considered as the primary test code for this set of charts. As indicated in the cyan instructions at the bottom of the screen, this test code name will be used as part of the data file created.
- 7.2.1. Enter from one to six test codes. Normally, two test codes will be entered; one for recovery and one for duplicate recovery (i.e. \$LR... and \$L2...).
- 7.2.2. If analytes from several base codes are to be charted together, enter them all here. For example, recoveries for Methods 608 and 8081/8082 waters are to be charted

Phillip G. Mitchell, QA Manager

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together, therefore six test codes would be entered (\$LR608, \$L2608, \$LR8081H, \$L28081H, \$LR8082H and \$L28082H). The spreadsheet will combine analytes with the same name into a single chart.

- 7.2.2.1. This approach may be used if test code names have changed during the charting period in order to combine all of the data points into a single chart.
- 7.2.2.2. Do not mix different types of test codes (different units, etc.). Do not mix recovery and precision test codes together.
- 7.2.2.3. Case is not important. The program can use "\$lr524v" or \$LR524V" equally well.
- 7.3. Enter the start date for the charting period in the box labeled "Start Date"
- 7.4. Enter the ending date plus one day for the ending date of the charting period in the "End Date + 1 Day" box.
- 7.4.1. For example, for the charting period January 1, 2009 to December 31, 2010, a start date of 1/1/09 and an end date of 1/1/11 would be entered.
- 7.4.2. These boxes will also allow the user to pick the dates from calendar boxes.
- 7.4.3. The specific numerical day, month or year in a date box may be changed by clicking on that part of the date.

End Date + 1 Day

7.5. Select the semester in which the charting is to be performed and to which it is to apply from the "Select Year/Semester" dropdown box:



7.5.1.

7.4.3.1.

7.6. Select the laboratory from the "Laboratory" dropdown box:



7.6.1 Semester

7.7. As an example, should recoveries for Methods 608 and 8081/8082 waters for the first semester of 2011 be desired, the completed screen might appear as follows:

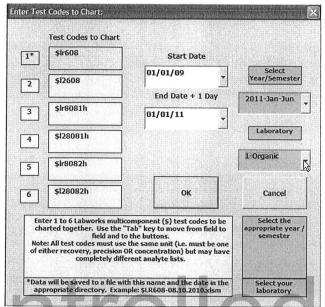
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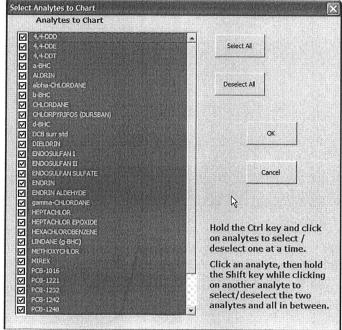
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7.7.1

- 7.8. Click "OK" to continue.
- 7.8.1. Please be patient. It may take a few moments for the next screen to be presented.
- 7.9. The next screen offers an opportunity to select or deselect specific compounds.



7.9.1.

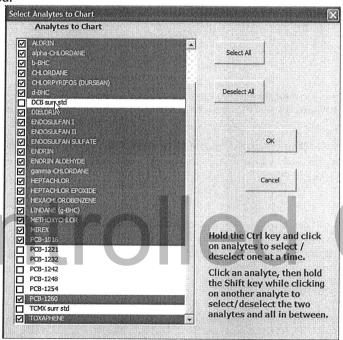
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7.9.2. In this example, surrogates are not to be charted. Several of the PCBs are never used as spikes and could be deselected as well. To deselect only the surrogates and specific PCBs, hold the control key and click on each of the surrogates to deselect them. If you make a mistake, use the "Select All" and/or "Deselect All" buttons as needed.



- 7.9.2.1.
- 7.9.3. When the correct list of analytes has been selected, click "OK" to continue.
- 7.9.3.1. *Please be very patient.* If there are hundreds of points and many analytes, this process may take several minutes to complete.
- 7.10. When the spreadsheet has completed processing the control charts, the main screen as shown in Section 5.1 above will be displayed and reset so that more charts may be processed.
- 7.11. A new spreadsheet named for the primary test code plus the date processed, will also be open. This new spreadsheet consist of worksheets for each analyte processed.
- 7.12. Save the new spreadsheet <u>without changing the path or name</u>. The spreadsheet will be saved to:
- 7.12.1. S:\CCData\<semester>\<laboratory>\<file name>
- 7.12.2. For example, the new spreadsheet created for pesticides (608/8081/8082) above would be saved to "S:\CCData\2011-Jan-Jun\1-Organic\\$LR608-01.14.2011.xlsm".
- 7.13. Review and correct each compound for outliers (see Section 9).
- 7.14. To conserve paper and reduce filing space, please print as follows:

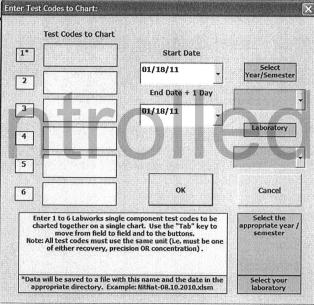
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- 7.14.1. The print ranges are automatically set to print the charts and the list of data points. Do not change the print range settings.
- 7.14.2. Select all of the worksheets by holding the "Ctrl" key and clicking on each tab, or by clicking on the tab on one end, scrolling to the other end, holding the "Shift" key and clicking the tab at the other end.
- 7.14.3. With <u>all</u> of the tabs selected, print by going to the Excel "File" tab and selecting to print or by pressing "Ctrl" + P.
- 7.14.4. <u>Please set up and print to a printer capable of double-sided printing or duplex printing to save paper!</u>
- 8. Single Component Control Charts
- 8.1. If single component charting is selected, the following screen will be presented:



Copy

- 8.1.1.
- 8.2. Test codes are entered in the cells labeled 1 6. The first cell ("1*") should be considered as the primary test code for this set of charts. As indicated in the cyan instructions at the bottom of the screen, this base test code name (the part after the QC test code letters, LR, R, etc.) will be used as part of the data file created.
- 8.2.1. Enter from one to six test codes. Normally, two test codes will be entered; one for recovery and one for duplicate recovery (i.e. LR... and L2...).
- 8.2.2. Analytes from the entire list of test codes entered are charted together on one chart. Points from test codes can be with different base names may be charted together, if appropriate. For example, LRNITNAT, L2NITNAT, LRNO3NO2, L2NO3NO2 could all be combined in one chart.
- 8.2.2.1. This approach may be used to combine data when test code names have changed during the charting period.

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- 8.2.2.2. Do not mix different types of test codes together (different units, etc.). Do not mix recovery and precision test codes together.
- 8.2.2.3. Case is not important. The program can use "Irnitnat" or "LRNITNAT" equally well.
- 8.3. Enter the start date for the charting period in the box labeled "Start Date"
- 8.4. Enter the ending date plus one day for the ending date of the charting period in the "End Date + 1 Day" box.
- 8.4.1. For example, for the charting period January 1, 2009 to December 31, 2010, a start date of 1/1/09 and an end date of 1/1/11 would be entered.
- 8.4.2. These boxes will also allow the user to pick the dates from calendar boxes.
- 8.4.3. The specific numerical day, month or year in a date box may be changed by clicking on that part of the date.

End Date + 1 Day

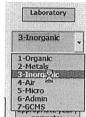
8.4.3.1.

8.5. Select the semester in which the charting is to be performed and to which it is to apply from the "Select Year/Semester" dropdown box:



8.5.1.

8.6. Select the laboratory from the "Laboratory" dropdown box:



8.6.1.

8.7. As an example, should combined recoveries for NITNAT and NO3NO2 waters for the first semester of 2011 be desired, the completed screen might appear as follows:

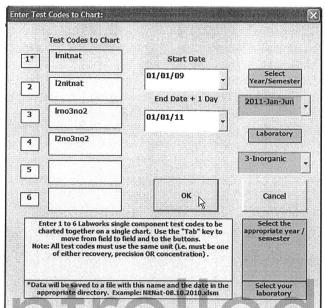
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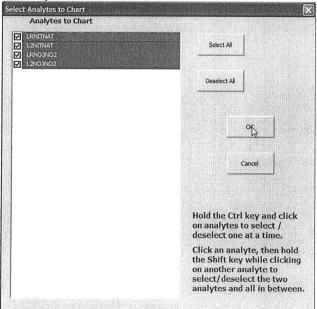
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3.7.1

- 8.8. Click "OK" to continue.
- 8.8.1. Please be patient. It may take a few moments for the next screen to be presented.
- 8.9. The next screen offers an opportunity to select of deselect specific test codes/analytes.



Phillip G. Mitchell, QA Manager

8.9.1.

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- 8.9.2. To select or deselect any test code, hold the "Ctrl" key while clicking specific test codes or select a range of codes by clicking on one test code, then hold the "Shift" key down while clicking a code at the other end of the desired range. If you make a mistake, use the "Select All" and/or "Deselect All" buttons as needed.
- 8.9.3. When the correct list of analytes has been selected, click "OK" to continue.
- 8.9.3.1. *Please be very patient.* If there are hundreds of points, this process may take several minutes to complete.
- 8.10. When the spreadsheet has completed processing the control charts, the main screen as shown in Section 5.1 above will be displayed and reset so that more charts may be processed.
- 8.11. A new spreadsheet named for the primary test code plus the date processed, will also be open. This new spreadsheet consist of one worksheet with the combined points of all the test codes processed.
- 8.12. Save the new spreadsheet <u>without changing the path or name</u>. The spreadsheet will be saved to:
- 8.12.1. S:\CCData\<semester>\<laboratory>\<file name>
- 8.12.2. For example, the new spreadsheet created for nitrates/nitrites (NITNAT/NO3NO2) above would be saved to "S:\CCData\2011-Jan-Jun\3-Inorganic\NITNAT-01.14.2011.xlsm".
- 8.13. Review and correct each compound for outliers (see Section 9).
- 8.14. To conserve paper and reduce filing space, please print as follows:
- 8.14.1. Select the first tab with a chart and press "Ctrl" + P.
- 8.14.2. Set the pages to be printed as page 1 to page 1. This prints the chart page only without printing any data points. <u>Please save some trees and DO NOT print the</u> data points!
- 8.14.3. Once set up to print only page 1, this setting will carry over to all of the other tabs.
- 9. Outliers
- **9.1.** Outliers are points that are outside certain limits and skew the calculated limits unreasonably.
- **9.1.1.** For recoveries, outliers are determined as follows:
- **9.1.1.1.** Any result 200% or higher is an outlier.
- **9.1.1.2.** Any result that is 50% or less the default LCL is an outlier.
- **9.1.2.** For precision, outliers are determined as follows:
- **9.1.2.1.** Any result 75% RPD or higher is an outlier.
- **9.1.2.2.** No precision result should ever be less than zero, the lower limit for precision. Therefore, there should never be outliers below the LCL.
- **9.2.** Review the charts for outliers. If an outlier exists, find the result in the list of data points below the chart, click on the "Result" cell for that point and press "Delete". The result must be deleted; a space or other non-visible character in the "Result" cell will adversely affect the control limits calculations.



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- **9.3.** Save and print the control chart(s) as described in Sections 5.12 5.14.4 for multicomponent charts or Sections 6.12 6.14.4 for single component charts.
- 10. *Fill out a Continuing Demo Form for Control Charting*. This applies to all Managers, Supervisors and Analysts who produce control charts during this cycle. See example below.
- 10.1. Class of Analytes is "Control Charts"
- 10.2. Cross out "Soil" (initial and date, of course) and write "NA".
- 10.3. Method Reference is "NA", but initial/date in the provided spaces.
- 10.4. MSDS Review is "NA" (you will have to hand write it in). Initial/date.
- 10.5. Waste Stream Source is "NA" for the first field. The rest of the table should be left blank.
- 10.6. Method Proficiency should not have anything checked except for <u>Procedure Requirements Met</u>. The Yes box should be checked, **but only if you have performed steps in Sections 1 and 2 above.**
- 10.7. Comments should say "No method proficiency requirements. SOP and instruction memo of 7/21/2011 read and understood."
- 10.8. Supporting Documentation should have No checked and the explanation "NA".
- 10.9. See following two pages for an example CDC form:



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		Continuing Demonstration of Capability Form (CDF) Chemical Analysis			orm (CDF)		
		Date: 01/19/2011	Supervisor Approval (N	A) – Initials:	Date:		
			Manager Approval –	Initials:	Date:		
			QA Manager Approval –	Initials:	Date:		
		Effective Date:	-				
		Analyst Name: Philli	p Mitchell	Position Number:	703971		
		Class of Analytes: Co	ontrol Charts	Matrix: Soi			
		Documentation Review					
		Method Reference(s): NA					
		"I have reviewed the method(s). I am familiar with terminology, acronyms, and requirements of the method(s)."					
			Analyst Initials:	Date:			
	100						
Ur		SOP(s) - Title(s) & Revision(s): Control Charts and Control Limits SOP 6-025 Rev. 0					
		"I have reviewed the SOP(s). I am familiar with and understand the					
		icronyms, and requirements o	and requirements of the SOP(s). I am aware of,				
		and understand the reasons for any discrepancies or contradictions between the method(s) and the SOP(s)."					
		between the n	Analyst Initials:	Date:			
		Quality Assurance Pl	an (QAP) – Date and Revision	a: August 2007 Rev	7. 7		
		"I have partici months."	pated in ongoing training on	the QAP within the	last six		
		242 1000.	Analyst Initials:	Date:			
		MSDS Review(s):					
		"I have reviewed the MSDSs for all chemicals associated with this procedure. I understand the health and safety risks associated with each chemical, including steps that should be taken in the event of a spill or accident involving these chemicals.					
	10.11.		Analyst Initials:	Date:			

10.11.

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:							
	Waste Stream(s) - EPD Laboratory Waste Management SOP, SOP 6-015 Rev. 0 Tables 6.1 - 6.7:						
Waste streams and final disposition of the wastes associated with this procedure:							
Waste Stream Source	Primary Waste Stream Hazardous Components	Final Laboratory Disposition					
N2	I STATE OF THE STA						
	Lind						
Method Proficiency The analyst has analyzed and met continuing demonstration criteria by one of the following: 1.) Reference Sample Recovery: Analyst has successfully performed the procedure on four reference samples achieving required accuracy and precision: Accuracy: Individual - Yes NA Average - Yes NA Precision (20% RSD unless otherwise specified): - Yes NA 2.) Unknown (Blind) Sample Analysis within Control Limits 3.) Passing results for the analysis of a Performance Evaluation Sample 4.) Passing MDL Study Procedure Requirements Met: Yes No If no explain: Comments: No proficiency requirements. Control Charting SOP and Memo of 1/19/11 read and understood Supporting Documentation Copies of all raw data necessary to reconstruct and validate these analyses are attached: Yes No If no explain:							

11. Determining Control Limits:

11.1. Using the guidelines in Section 2.3 of the SOP and those below, either circle the printed control limits or write adjusted limits in the boxes under the calculated limits.

Do not cross-out/correct the printed values. In-house control limits will be set based on LCS, MS and Sample Surrogate recoveries and LCS/LCSD and MS/MSD

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precisions. MS/MSD recovery and precision limits will not be developed for SOPs that do not currently have published limits for MS/MSD precision and accuracy.

11.1.1. Rather than setting arbitrary limits as described by the SOP, use the following table to determine maximum and minimum values for LCLs and UCLs:

following table to determine maximum and minimum values for LC				
Default Values from	In-house Calculated	In-house Calculated		
Methods	Limits Tolerance	Limits bound by		
		Method		
If the Default $LCL =$	In-house Maximum	In-house Minimum		
	LCL =	LCL=		
>= 90	95	Method default LCL		
>= 80 and < 90	90	Method default LCL		
>60 and <= 80	85	Method default LCL		
<= 60	80	Method default LCL		
<=10	80	10		
If the Default $UCL =$	In-house Minimum	In-house Maximum		
	UCL =	UCL =		
< 100	100	100		
<= 110	105	Method default UCL		
>110 and $<= 120$	110	Method default UCL		
>120 and <= 130	115	Method default UCL		
>= 131	120	Method default UCL		
If the Default Precision	In-house Minimum			
Upper Limit =	Precision Limit =			
>= 10% RPD	10% RPD			
< 10% RPD	Method default			
	maximum %RPD			
1.2 Example: The method default limits are 95 1150/				

- 11.1.2. Example: The method default limits are 85 115% recovery. The calculated limits are 92 123%. For a default LCL of >= 80% and < 90%, the maximum LCL is 90%, which is less than the calculated 92%. Therefore the LCL is set to the 90% limit. For the default UCL of > 110% to <= 120%, the maximum UCL is method default UCL, in this case 115%.
- 11.1.3. Example: The method default maximum %RPD is 30%. The LCL is always zero for precision. The calculated UCL is 38% RPD. The in-house UCL for %RPD is 30%, the method maximum.
- 11.1.4. In-house LCLs and UCLs for recovery and precision are rounded to the nearest integer using unbiased rounding for a number followed by exactly 5 (also called "rounding to the even"; 2.5 rounds to 2; 3.5 rounds to 4).
- 11.2. If there are no method default limits, in-house default limits will be set. Most of these were determined in the last charting session.
- 11.2.1. Use the default limits assigned on the "Control Limits Update Report" coversheets developed in the last charting round.
- 11.2.2. Develop tables that can be inserted in the SOPs to more appropriately and conveniently document the default control limits. Be sure to indicate any limits that are in-house defaults as opposed to method defaults.



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11.2.3. Some example table entries (several methods are mixed together in the following table) might be as follows:

Analyte	Default LCL	Default UCL
Dalapon*	40	160
DCAA (SS)**	60	140
Alachlor *** (R= 95)	65	125
EDB	70	130

*Refer to Section 10.3.2 and Table 2 of EPA Method 515.1 Revision 4.0 1989

**In-house determined limits

***Refer to Section 9.3.2 and Table 2 of EPA Method 507 Revision 2.1 1995

- 11.2.3.1. Dalapon default limits are described in the referenced section of the method and determined by Table 2 of the method.
- 11.2.3.2. DCAA (SS) is a surrogate with no method default limits, therefore in-house limits were assigned. These limits were documented during the last round of charting.
- 11.2.3.3. Alachlor default limits are described in the referenced section of the method as being \pm 30% of the value R assigned to each compound in Table 2 of the method.
- 11.2.3.4. EDB (Method 504) and all other analytes in that method have default control limits of 70 13-% as described in Section 9.3.2 of the method.
- 12. Collect the printouts and organize as follows:
- 12.1. CDC form on top. This only needs to be added to one set of charts. See Section 10.
- 12.2. Charts are next.
- 12.3. Clip the package together. Do not staple any part of the package!
- 12.4. Charts are to be produced for LCS/LCSD, MS/MSD recoveries and precision. Also, for methods with surrogates, repeat on the main test code (all regular samples as opposed to QC samples) selecting only the surrogates for charting in as indicated in Sections 7.9 and 8.9.

13. Additional notes:

- 13.1. Initial and date each QC chart produced.
- 13.2. No limits are to be updated in Labworks until the QA Manager has approved charts and SOPs updated and distributed.

